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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/992,800	11/06/2001	Victor Raso	BBRI-2006	7805

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06/04/2003

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EXAMINER

PATTERSON, CHARLES L JR

ART UNIT

PAPER NUMBER

1652

DATE MAILED: 06/04/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/992,800

Applicant(s)

RASO, VICTOR

Examiner

Charles L. Patterson, Jr.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 37-106 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 37-106 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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Restriction to one of the following inventions is required under 35

U.S.C. 121:

- I. Claims 37-46, drawn to a bispecific antibody, classified in class 530, subclass 387.3.
- II. Claims 47-66, drawn to a method for inhibiting the formation of β -amyloid plaques or promoting the disaggregation of a preformed β -amyloid plaque, comprising introducing a bispecific antibody into the circulatory system, classified in class 424, subclass 133.1.
- III. Claims 68, 72-86, 94, drawn to a therapeutic antibody that specifically binds an epitope in positions 10-25 of $A\beta$ and an antibody fragment, classified in class 530, subclass 387.9.
- IV. Claims 69, 72-75, 77-86, 94, drawn to a therapeutic antibody that sequesters $A\beta$ peptide from its circulating form in blood, alters clearance of soluble and bound forms in the central nervous system and plasma and an antibody fragment, classified in class 530, subclass 387.9.
- V. Claims 70, 72-75, 77-86, 94, drawn to a therapeutic antibody that sequesters free β -amyloid in the blood and impedes passage of soluble β -amyloid out of the peripheral circulation and an antibody fragment, classified in class 530, subclass 387.9.
- VI. Claims 71-75, 77-86, 94, drawn to a therapeutic antibody that sequesters free β -amyloid in the blood, reduces levels of β -amyloid in the brain and prevents formation of amyloid plaques in the brain and an antibody fragment, classified in class 530, subclass 387.9.
- VII. Claims 87-94, drawn to a nucleic acid encoding the antibody of claims 68, 72-86, classified in class 536, subclass 23.53.

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VIII. Claims 87-94, drawn to a nucleic acid encoding the antibody of claims 69, 72-75 and 77-86, classified in class 536, subclass 23.53.

IX. Claims 87-94, drawn to a nucleic acid encoding the antibody of claims 70, 72-75 and 77-86, classified in class 536, subclass 23.53.

X. Claims 87-94, drawn to a nucleic acid encoding the antibody of claims 71-75 and 77-86, classified in class 536, subclass 23.53.

XI. Claims 95-105, drawn to a method to inhibit the formation of amyloid plaques or the effects of toxic soluble A β species, comprising administering a therapeutic antibody or fragment that specifically reacts with positions 10-25 or A β , classified in class 424, subclass 139.1.

XII. Claim 106, drawn to a method of treating Alzheimer's disease comprising administering an effective amount of antibody or fragment of claims 68-86, classified in class 424, subclass 139.1.

The inventions are distinct, each from the other because:

Inventions I and III-VI are completely different antibodies that are structurally different and as such are patentably distinct.

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process such as to bind to one of its binding specifici-

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ties to test for the presence of that moiety, not involving a treatment method.

Inventions (III-VI) and inventions (VII-X) are drawn to different chemical compounds that are patentably distinct.

The method of invention II are separate and distinct from the method of invention XI and XII since one method uses bispecific antibodies and the other does not.

Invention XI is patentably distinct from invention XII since the first group is involved in inhibition of formation of amyloid plaques or the effects of toxic A β species while the latter is involved the treating a particular disease.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles L. Patterson, Jr., PhD, whose telephone number is 703-308-1834. The examiner can normally be reached on Monday - Friday, 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 703-308-3804. The fax phone number is 703-308-4242.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Charles L. Patterson, Jr.
Primary Examiner
Art Unit 1652

Patterson
June 2, 2003